

R₁-X-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-
Ser-Tyr-Leu-Y-Gly-Gln-Ala-Ala-Lys-Z-Phe-
Ile-Ala-Trp-Leu-Val-Lys-Gly-Arg-R₂
(SEQ ID NO:1)

wherein:

R₁ is histidine;

X is Gly, Val, Thr, Ile, or alpha-methyl-Ala;

Y and Z are each Glu; and

R₂ is NH₂ or Gly-OH;

said method comprising the step of [,]
administering an effective amount of [a] the GLP-1
molecule, or a pharmaceutically-acceptable salt of the
GLP-1 molecule, [selected from the group consisting of
GLP-1, GLP-1 analogs, or GLP-1 derivatives] to a
patient in need thereof by pulmonary means.

2. The method of **Claim 1**, wherein the GLP-1 molecule is delivered to lower airway[als] of the patient.

18. A method of administering [The method of Claim 17,
wherein the GLP-1 analog is selected from the group
consisting of] Val⁸-GLP-1(7-37)OH, Gly⁸-GLP-1(7-37)OH
or [and] Asp⁸-GLP-1(7-37)OH, comprising administering
an effective amount of Val⁸-GLP-1(7-37)OH, Gly⁸-GLP-
1(7-37)OH or Asp⁸-GLP-1(7-37)OH or a pharmaceutically
acceptable salt thereof, to a patient in need thereof
by pulmonary means.

- Q2
Conclude
19. A method of administering [The method of Claim 18,
wherein the GLP-1 analog is] Val⁸-GLP-1(7-37)OH,
comprising administering an effective amount of Val⁸-
GLP-1(7-37)OH, or a pharmaceutically acceptable salt of
Val⁸-GLP-1(7-37)OH, to a patient in need thereof by
pulmonary means.

- Q3
21. A method for treating a patient with diabetes,
comprising[,] administering an effective dose of a GLP-
1 molecule, or a pharmaceutically acceptable salt of
the GLP-1 molecule, to [a] the patient [in need
thereof] by pulmonary [delivery] means, said GLP-1
molecule having the amino acid sequence of SEQ ID NO:
1:

R₁-X-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-
Ser-Tyr-Leu-Y-Gly-Gln-Ala-Ala-Lys-Z-Phe-
Ile-Ala-Trp-Leu-Val-Lys-Gly-Arg-R₂
(SEQ ID NO:1)

wherein:

R₁ is histidine;

X is Gly, Val, Thr, Ile, or alpha-methyl-Ala;

Y and Z are each Glu; and

R₂ is NH₂ or Gly-OH.

- Q3
23. A method for treating a patient with diabetes,
comprising administering an effective dose of [The

a3
conclude

method of Claim 21, wherein the GLP-1 molecule is] Val⁸-GLP-1(7-37)OH or a pharmaceutically effective salt of Val⁸-GLP-1(7-37)OH, to the patient by pulmonary means.

a4

31. A method for treating a patient with hyperglycemia comprising, administering an effective dose of a GLP-1 molecule, or a pharmaceutically acceptable salt of the GLP-1 molecule, to [a] the patient [in need thereof] by pulmonary means, said GLP-1 molecule having the amino acid sequence of SEQ ID NO: 1:

R₁-X-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-
Ser-Tyr-Leu-Y-Gly-Gln-Ala-Ala-Lys-Z-Phe-
Ile-Ala-Trp-Leu-Val-Lys-Gly-Arg-R₂
(SEQ ID NO:1)

wherein:

R₁ is histidine;

X is Gly, Val, Thr, Ile, or alpha-methyl-Ala;

Y and Z are each Glu; and

R₂ is NH₂ or Gly-OH.

a5

33. A method for treating a patient with hyperglycemia, comprising administering an effective dose of [The method of Claim 31, wherein the GLP-1 molecule is] Val⁸-GLP-1(7-37)OH, or a pharmaceutically acceptable salt of Val⁸-GLP-1(7-37)OH, to the patient by pulmonary means.

a6

41. A method of administering a glucagon-like peptide-1(GLP-1) molecule, said method comprising the step of

administering an effective amount of the GLP-1 molecule, or a pharmaceutically acceptable salt of the GLP-1 molecule, to a patient in need thereof by pulmonary means, wherein said GLP-1 molecule has the amino acid sequence of GLP-1(7-34)OH, GLP-1(7-34)NH₂, GLP-1(7-35)OH, GLP-1(7-35)NH₂, GLP-1(7-36)OH, GLP-1(7-36)NH₂, GLP-1(7-37)OH or GLP-1(7-37)NH₂, modified by replacing alanine at position 8 with an amino acid having an uncharged side chain.

42. A method for treating a patient with diabetes, comprising administering an effective dose of a GLP-1 molecule, or a pharmaceutically effective salt of the GLP-1 molecule, to the patient by pulmonary means, wherein said GLP-1 molecule has the amino acid sequence of GLP-1(7-34)OH, GLP-1(7-34)NH₂, GLP-1(7-35)OH, GLP-1(7-35)NH₂, GLP-1(7-36)OH, GLP-1(7-36)NH₂, GLP-1(7-37)OH or GLP-1(7-37)NH₂, modified by replacing alanine at position 8 with an amino acid having an uncharged side chain or the amide form thereof.

43. A method for treating a patient with hyperglycemia, comprising administering an effective dose of a GLP-1 molecule, or a pharmaceutically acceptable salt of the GLP-1 molecule, to the patient by pulmonary means, wherein said GLP-1 molecule has the amino acid sequence of GLP-1(7-34)OH, GLP-1(7-34)NH₂, GLP-1(7-35)OH, GLP-1(7-35)NH₂, GLP-1(7-36)OH, GLP-1(7-36)NH₂, GLP-1(7-37)OH or GLP-1(7-37)NH₂, modified by replacing alanine at position 8 with an amino acid residue having an uncharged side chain or the amide form thereof.

REMARKS

Telephonic Interview

Examiner Lukton is thanked for granting the telephonic interview and for his helpful comments during the interview. It was agreed during the interview that the Examiner would